

Filtration bag intended to allow for the sterile filtration of blood and set of bags for blood collection.

The invention relates to a filtration bag, intended to allow for the sterile filtration of blood in order to separate its components.

The filtration bag consists of an outer sheath formed by an assembly of two plastic sheets 9, 10 assembled on their periphery 25. According to the invention, a filtering medium 11 is maintained in a flexible, impervious frame 12 that separate, the inside of the sheath into two compartments, respectively an inlet compartment 13 into and an outlet compartment 14 from the bag. The flexible frame 12 is formed by two perforated plastic sheets 17 and 18 between which the filtering medium 11 is placed. These sheets 17 and 18 are bonded at the welding run 19 at the periphery of the filtration medium 11 as well as at the periphery of the sheath of the bag 5.

The invention relates to the manufacturers of medical equipment.

The invention relates to a filtration bag intended to allow for the sterile filtration of whole blood or concentrates of red blood cells in order to remove the white blood cells, otherwise called leukocytes, as well as a set of bags for 5 the collection of blood using the aforementioned filtration bag. It concerns manufacturers of medical equipment.

The need for labile blood components free of leukocytes is increasing in hospitals. This is related to technical developments that improve the results and provide valuable 10 benefits for the state of health of the transfused.

Initially, the equipment that was used for the collection of blood mainly consisted of glass bottles that could be reused after sterilisation. The progress made in the field of plastics has enabled the replacement of these bottles by 15 flexible disposable bags. In addition to the greater convenience provided by the flexible bags, they also allow for, due to systems of multiple bags, the separation of the labile derivatives from the blood in a closed circuit, without the risk of septic contamination.

20 Currently, blood is collected using sterile bags, manufactured with flexible plastic sheets mutually welded along their periphery. The bags are connected to a blood drawing needle by means of a flexible tube and, in the case of multiple bags, to other secondary bags also by means of 25 flexible tubes.

By centrifugation or decantation, it is possible to separate the different components of the blood collected in the bag, that is, the plasma, the white blood cells and the red blood cells that separate into layers. It is then advisable to 30 distribute these different previously separated blood components in secondary bags connected to the collection

bag. Current techniques are perfectly adapted for this type of sterile closed-circuit separation.

When deleukocytation is required, that is, when it is necessary to remove the white blood cells from a labile 5 blood component that are potentially or undoubtedly noxious to the transfused patient, the use of a specific filter is a commonly used technique.

For this operation, a bag containing the blood component that has to be free of leukocytes is connected to a 10 secondary bag for the collection of the leukocyte-free component by means of a filter.

The filters currently available come in the form of a rigid box in which a filtering medium is integrated as well as a inlet tube ending in a perforator intended to provide the 15 connection with the bag containing the component that has to be filtered.

By nature, these rigid boxes can not be sterilised by steam and their use in centrifugation is difficult.

In addition, these rigid filtration boxes contain a quantity 20 of air that has to be removed upon completion of the filtration by a parallel tube in by-pass in order to avoid the filter made impervious to air by the inhibition of the filtering medium.

The main purpose of the present invention is to provide a 25 flexible filtration bag that has the same conveniences with use as the flexible collection and transfer bags commonly used.

Thereby, the filtration bag in the present invention may perfectly be sterilised by steam and be used in a 30 centrifuge. Moreover, the filtration bag can be immediately

integrated in a system of multiple bags to carry out filtrations in a closed-circuit under conditions of maximum asepsis since, at all times, connections have to be made between separate elements.

5 Another advantage of the present invention is that the suppleness of the filtration bag renders the evacuation of the residual air useless by means of a parallel tub in bypass.

10 The flexible outer walls tend to stick to the filtering medium, which may prevent the passage of the liquid to filter. Special care has been given this potential problem and was resolved by the interposition of flexible plastic rods between the flexible wall and the filtering medium.

15 Another advantage of the present invention is the transparency of the walls of the filtration bag allowing the user to perfectly see the stage of filtration and, in particular, the completion of the passage of the liquid for filtration.

20 Other purposes and advantages to the present invention will appear in the following description, which is nevertheless only provided by way of indication.

According to the invention, the filtration bag, intended to allow for the filtration of whole blood or a labile blood component, consists of a flexible outer sheath enclosing a 25 filtering medium. It is characterised in that the filtering medium is maintained in a flexible, impervious frame that separates two compartments, an inlet compartment and an outlet compartment respectively in the bag.

30 The invention will be better understood upon reading the following description accompanied by drawings in the appendix among which:

- figure 1 shows a set of bags intended for the collection of blood, its separation into different labile components and the filtration of the concentrate of red blood cells to ensure the depletion in white blood cells,
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- figure 2 shows, in a cross section, a filtration bag according to the present invention,
- figure 3 illustrates the placement of the filtering medium on a flexible frame,
- 10 - figure 4 shows the placement of the filtering medium in the bag,
- figure 5 shows the placement of the spread rods for the walls in the filtration bag.

The present invention relates to a filtration bag, intended
15 to allow for the deleukocytation of a labile blood component as well as a set of bags for blood collection using the aforementioned filtration bag. It mainly relates to the manufacturers of medical equipment and products.

The object of the present invention is a flexible filtration
20 bag that can be perfectly integrated in a system of flexible primary and secondary bags for the collection and separation of labile blood components. The filtration bag in the invention may also undergo sterilisation by steam and centrifugation of the bag system. Asepsis during all of the
25 operations for the separation of the blood components is provided since the closed circuit is never open to the outside.

Figure 1 shows a system of bags more specifically adapted to a depletion in leukocytes of a concentrate of red blood cells obtained by the separation of a whole blood unit. A
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collection needle 1 for introduction in the donor's vein is connected by a flexible tube 2 to a flexible main bag 3 in which the blood is collected. This main bag 3 containing an anticoagulant solution is connected to a secondary bag 4 for the collection of red blood cells by way of an intermediate filtration bag 5, the object of the present invention.

Moreover, the main bag 3 is, for example, also connected to secondary bags 6 and 7 by means of a set 8 of flexible tubes towards which the platelet-rich plasma and the platelet-poor plasma separated by centrifugation are respectively directed according to techniques familiar to the specialist.

Of course, the flexible filtration bag 5 in the present invention may also have other applications. Nevertheless, it is already possible to discern the advantages here, that is, the possibility of overall sterilisation of the set of bags by steam and the transfer of blood derivatives without opening the circuit to free air. In addition, the filtration bag can perfectly undergo centrifugation without damage to itself or other bags contained at the same time in the same centrifugation machine.

Figure 2 shows a longitudinal cross-section of the filtration bag 5 in the invention. It comprises a flexible outer sheath formed by an assembly of two plastic sheets 9 and 10 mutually assembled on their periphery. This outer sheath encloses a filtering medium 11 that, according to the invention, is maintained in a flexible, impervious frame 12 that separates two compartments, the inlet compartment 13 and the outlet compartment 14 of the filtration bag 5 respectively.

Compartment 13 communicates with the outside of the bag 5 by means of a flexible inlet tube 15 that is used to fill the filtration bag. Compartment 4 communicates with the outside

of bag 5 by means of a flexible outlet tube 16 that provides for the evacuation of the filtered fluid.

Therefore, according to the present invention, the difficulties of impermeability are resolved on two levels.

5 First, a first impermeability is provided between the filtering medium 11 and the flexible frame 12 where there is no passage of tube but where it is necessary to provide a junction between different types of materials, that is, the filtering medium and a plastic frame 12. Then, the second
10 level of impermeability that has to be provided is at the periphery of the filtration bag 5 where a junction has to be provided between the outer sheets 9 and 10, the periphery of the flexible frame 12 and the passage of flexible inlet tubes for liquids 15 and outlet tubes for liquids 16.

15 This second level of impermeability required may also be provided according to techniques familiar to specialists if the design of the bag is based on the use of flexible plastic sheets 9 and 10 and a flexible frame 12. The same flexible plastic is used for the inlet tube 15 and the
20 outlet tube 16. Among the known techniques, it is possible, for example, to mention high frequency welding.

Figure 3 shows a partial cross-section of the design of the flexible frame 12 to support the filtering medium 11. This frame 12 is formed by an assembly of two plastic sheets 17 and 18 between which the filtering medium 11 is placed. The central part of these two sheets 17 and 18 is perforated and each one has at least one opening 23, 24 so that the filtering medium 11 can communicate with each side.
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Sheets 17 and 18 are attached at the periphery of the filtering medium 11, for example by a weld run 19. The advantage of using a peripheral weld run 19 is that it not only provides fixation of the filtering medium 11 to the
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centre of the flexible frame 12, but it also forms a peripheral seal that prevents liquids from flowing between the sheets 17 and 18.

Figure 4 shows a cross-section of the flexible filtrating bag 5 in the present invention. The welding of sheets 17 and 18 through the filtering medium 11 that is highly compressed at this level to form an impervious strand 19 can be noted.

The periphery 25 of the flexible frame 12 is mutually welded with external sheets 9 and 10 along their periphery, that form the sheath of filtration bag 5. The impermeability is, as a result, provided at this level.

The filtering medium 11 may be made, for example, by juxtaposition of the filtration layers. For example, the number of layers can range from four to twenty. It is also advantageous to use a grid-shaped or non-woven pre-filter 20 with a porosity exceeding the outside of the filtering medium 11 to avoid it clogging up.

It has been noted that the filtering medium 11 may tend to stick to the outer wall 10 of the sheath that forms the outlet compartment 14. This may hinder the passage of fluids.

To correct this defect, it is advantageous, for example, to place two rods 21 and 22 inside the sheet 10 that forms the outlet compartment 14 to avoid allowing the outer layer of the filtering medium 11 to come up against the inner wall of the sheet 10.

In practice, the rods 21 and 22 are in particular formed by flexible tubes welded at the inner wall of the sheet 10, in particular at the peripheral weld 25 of the filtration bag 5, as illustrated in figure 5. These rods 21 and 22 allow

the sheet 10 to be separated from the filtering medium 11. Thanks to their flexibility, the rods 21 and 22 do not alter the folding properties of the filtration bag 5.

Other aims and advantages of the present invention,
5 available to the specialist, will also be considered without departing from the scope of the invention.

CLAIMS

- 5 1. A filtration bag (5), intended to allow for the filtration of whole blood or labile blood components in order to separate the white blood cells that comprises a flexible outer sheath formed by two flexible plastic sheets (9, 10) assembled along their periphery (25) enclosing a filtering medium (11), characterised in that the filtering medium (11) is maintained in a flexible, impervious frame (12) that separates two compartments (13, 14), an inlet into and an outlet compartment from the filtration bag (5) respectively.
- 10 2. A filtration bag according to claim 1, characterised in that the frame (12) is formed by an assembly of two flexible perforated sheets (17 and 18) between which the filtering medium (11) is placed.
- 15 3. A filtration bag according to claim 2, characterised in that the sheets (17, 18) that form the frame (12) are attached along the periphery (19) of the filtering medium (11) and also with the sheets (9, 10) at the periphery (25) of the sheath of the filtration bag (5).
- 20 4. A filtration bag according to claim 3, characterised in that the fixation of the sheets (17, 18) that form the flexible frame (12) is a welding run (19) created through the filtering medium (11).
- 25 5. A filtration bag according to claim 1, characterised in that the filtering medium (11) comprises an outer pre-filter (20) that is provided in the form of a grid.

6. A filtration bag according to claim 1, characterised in that the outlet compartment (14) is separated from the filtering medium (11) by the presence of flexible spread rods (21 and 22).
- 5 7. A filtration bag according to claim 6, characterised in that the flexible spread rods (21 and 22) are formed by welded tubes at the inner wall of the sheet (10) of the filtration bag.
- 10 8. A set of bags for blood collection, more specially adapted to deleukocytation, comprising a filtration bag (5) according to any of the previous claims.